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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BURLINGTON DRUG CO., INC.
on behalf of itself and all others
similarly situated,

Plaintiff,

V.

**PFIZER INC., WARNER-LAMBERT
CO., AND RANBAXY, INC.**

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Burlington Drug Co., Inc., 91 Catamount Drive, Milton, Vermont 05468 (“Plaintiff”) on behalf of itself and all others similarly situated, for their Complaint against defendant Pfizer Inc. (“Pfizer”), 235 East 42nd Street, New York, New York 10017 and its subsidiary Warner-Lambert Co. (“Warner-Lambert”), 235 East 42nd Street, New York, New York, 10017; and defendant Ranbaxy Inc. (“Ranbaxy”), 600 College Road East, Princeton, New Jersey, 08540 allege as follows based on: (a) personal knowledge; (b) the investigations of counsel; and (c) information and belief:

I. NATURE OF THE ACTION

1. Pfizer is the largest pharmaceutical company in the world. It is the largest biopharmaceutical company in four global markets: the United States, the European Union, Japan and Latin America. It is also the largest United States-headquartered biopharmaceutical company in what Pfizer describes as the “Emerging Markets” of Asia, the Middle East, Africa, central and eastern Europe, Russia, Turkey and South Korea.

2. Lipitor is a Drug used to treat high cholesterol, containing atorvastatin calcium as its active ingredient. Lipitor was purchased by Pfizer as part of its acquisition of Warner Lambert in 2000.

3. Lipitor is the best-selling drug in the history of the pharmaceutical business.

4. Lipitor sales under Pfizer’s regime were over \$13 billion per year worldwide, more than \$1 billion per month. Of Pfizer’s total annual revenue from Lipitor, up to \$7 billion per year was from the United States alone. Sixteen million Americans take Lipitor every day.

5. Lipitor has constituted 20-30% of the total revenues of Pfizer since 2006 or earlier. For several years, defendant Pfizer has enjoyed billions of dollars in revenue and profits from the prescription drug Lipitor.

6. Pfizer originally listed five (5) patents in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for Lipitor: U.S. Patent No. 4,681,893 (“the ‘893 patent”); U.S. Patent No. 5,273,995 (“the ‘995 patent”); U.S. Patent No. 6,126,971 (“the ‘971 patent”); U.S. Patent No. 5,686,104 (“the ‘104 patent”); and U.S. Patent No. 5,969,156 (“the ‘156 patent”). On March 17, 2009, the ‘995 patent was reissued in part as U.S.

Patent No. 40,667 (“the ‘667 patent”); Pfizer has since listed the ‘667 patent in the Orange Book as well.

7. The ‘893 patent, which was the patent on the active ingredient in Lipitor (atorvastatin calcium), expired on March, 24, 2010.

8. The ‘995 patent (reissued as the ‘667 patent), an enantiomer patent on a particular form of the Lipitor molecule, expired on June 28, 2011.

9. Pfizer and its subsidiaries also own two process patents – U.S. Patent No. 6,087,511 (“the ‘511 patent”) and U.S. Patent No. 6,274,740 (“the ‘740 patent”) – that claim a process for making amorphous atorvastatin calcium that is limited to crystalline Form I atorvastatin calcium (the ‘511 patent and the ‘740 patent are collectively referred to as “the Process Patents”). Pfizer has not listed these patents in the Orange Book; it has sued to enforce these patents on only two occasions, against only two generic competitors.

10. In 2003, Ranbaxy, the largest pharmaceutical company in India, developed a generic version of Lipitor. In order to sell its generic in the United States in competition with Lipitor, Ranbaxy challenged the validity of the Lipitor patents listed in the Orange Book.

11. Because Ranbaxy was the first to challenge the validity of the listed Lipitor patents, under the 1984 Hatch-Waxman law Ranbaxy gained the exclusive right to sell its generic and exclude all other generics for 180 days after either the first commercial launch of a generic Lipitor product or the entry of a final court decision declaring the Lipitor patents invalid or not infringed.

12. Facing a dramatic reduction in future revenue with the loss of exclusivity of Lipitor, Pfizer entered into an unlawful agreement with Ranbaxy to delay the entry of generic versions of Lipitor into the United States for up to 20 months after its patents had expired.

13. The fundamental terms of this agreement were that Ranbaxy would not enter the United States market with its Lipitor generic until November 2011. By agreeing to delay entry, Ranbaxy maintained the bottleneck, preventing other generics from entering the United States market until the summer of 2012 or later. In return, Ranbaxy was authorized to sell generic Lipitor in several other countries. Pfizer also agreed to drop its challenge of Ranbaxy's current sale of a generic version of Lipitor in several countries, and Pfizer cancelled a Ranbaxy judgment debt arising from another case.

14. In order to disguise the anticompetitive nature of this agreement, Pfizer initiated litigation against Ranbaxy for infringement of the Process Patents, even though Pfizer and Ranbaxy both knew, from a ruling by a Delaware District Court Judge in a related action, that Pfizer did not have standing to bring this litigation because Ranbaxy had already been enjoined from manufacturing generic Lipitor and therefore could not, as a practical matter, infringe the Process Patents. This litigation, which was initiated in March of 2008, was speedily resolved in June of 2008.

II. JURISDICTION AND VENUE

15. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and the costs of suit, including a reasonable attorneys' fee, for the injuries sustained by Plaintiff and members of the class resulting from violations by the Defendants, as hereinafter alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

16. The Defendants named herein are found or transact business within this judicial district, and the interstate trade and commerce, hereinafter described is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

17. Plaintiff Burlington Drug Co., Inc. is a corporation organized under the laws of the State of Vermont and is located at 91 Catamount Drive, Milton, Vermont, 05468. Burlington Drug Co. purchased Lipitor directly from Pfizer, Inc during the Class Period as defined below, and was injured by the illegal conduct described herein.

18. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York, 10017. Pfizer is in the business, among other things, of developing, manufacturing, distributing, advertising, and selling Lipitor throughout the United States.

19. Defendant Warner-Lambert Company is a wholly-owned subsidiary of Pfizer, and is located at 235 East 42nd Street, New York, New York, 10017. Warner-Lambert was an independent public company until June 2000, when it was acquired by Pfizer. Defendant Warner Lambert has been the owner of record of the relevant patents covering Lipitor since their issuance.

20. Defendant Ranbaxy, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540.

21. Upon information and belief, Ranbaxy, Inc. was formerly known as Ranbaxy Pharmaceuticals, Inc., and is a wholly owned subsidiary of Ranbaxy Laboratories.

IV. CLASS ACTION ALLEGATIONS

23. Plaintiff brings this action on behalf of themselves and, under Rule 23 of the Federal Rules of Civil Procedure, as representatives of a class defined as follows:

All persons or entities in the United States and its territories who directly purchased Lipitor from Defendant at any time during the Class Period of March 24, 2010 until the effects of Defendants' conduct ceases (the "Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

24. Members of the Class are so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff, it is believed to be at least in the hundreds. Furthermore, the Class is readily identifiable from information and records in the possession of Defendants.

25. Plaintiff's claims are typical of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by the Defendants; i.e., they have paid artificially inflated prices for atorvastatin calcium and were deprived of the benefits of competition from cheaper generic versions of Lipitor as a result of Defendants' wrongful conduct.

26. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

27. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, particularly class action antitrust litigation in the pharmaceutical industry.

28. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because the Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

29. Questions of law and fact common to the Class include:

- a. whether the conduct alleged herein constitutes a violation of the antitrust laws;
- b. whether a relevant market needs to be defined in this case in light of the existence of direct evidence of Pfizer's power to exclude generic competition and supracompetitive prices for atorvastatin calcium;
- c. if a relevant market needs to be defined, the definition of the relevant market for analyzing Pfizer's monopoly power, and whether Pfizer had monopoly power in the relevant market;
- d. whether Defendants' actions illegally maintained Defendants' monopoly power in the relevant market;
- e. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and
- f. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of its direct purchaser customers and if so, the appropriate measure of damages.

30. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

31. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. REGULATORY AND ECONOMIC BACKGROUND

32. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392) a manufacturer who creates a new, pioneer drug must obtain the approval of the Food and Drug Administration (“FDA”) to sell the new drug by filing a New Drug Application (“NDA”). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents. A manufacturer may only promote uses for a drug that are approved by the FDA.

33. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (“Hatch-Waxman”).

34. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to

obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application (“ANDA”).

35. The ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer must show the FDA that the generic drug it is going to market is chemically equivalent to the brand-name drug.

36. As a counter-balance, Hatch-Waxman streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided the brand-name manufacturer with what is essentially a preliminary injunction, in the form of a 30-month stay of FDA approval of generic manufacturer’s ANDAs.

37. When the FDA approves a brand-name manufacturer’s NDA, the FDA publishes any patents which, according to information supplied to the FDA by the brand-name manufacturer, claim the approved drug or its approved uses, in a publication entitled the “Approved Drug Products with Therapeutic Equivalence Evaluations,” known as the “Orange Book.” 21 U.S.C. §355(j)(7)(A)(iii). The FDA does not check the facts supplied to it by the brand-name manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand-name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand-name manufacturer similarly certifies that the new patents claim either the approved drug or its approved uses.

38. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA does not violate any patent listed in the Orange Book as claiming the brand-name drug.

39. Under Hatch-Waxman, a generic manufacturer’s ANDA must contain one of four certifications:

- a. that no patent for the brand-name drug has been filed with the FDA;
- b. that the patent for the brand-name drug has expired;
- c. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a “paragraph III certification”); or
- d. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer’s proposed product (a “paragraph IV certification”).

21 U.S.C. §355(j)(2)(A)(vii).

40. Alternatively, an ANDA may assert that a patent is inapplicable to the indication for which the drug product will be marketed (called a “section viii statement”).

41. If a generic manufacturer files only a paragraph III certification, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. §355(j)(5)(A). If the FDA approves the ANDA, the approval can become effective on the date certified as the patent expiration date. 21 U.S.C. §355(j)(5)(B)(ii).

42. If a generic manufacturer files a paragraph IV certification that the listed patent is invalid or will not be infringed, then the brand-name manufacturer has the opportunity to slow the process down. This is because a generic manufacturer filing a paragraph IV certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue. The generic manufacturer’s act of filing a paragraph IV certification triggers the time by which a patent owner may file an action for patent infringement, and take advantage of an automatic 30-month stay of FDA approval of the generic version of the NDA owner’s drug.

43. If the patent owner fails to initiate a patent infringement action within 45 days after receiving notice of the generic manufacturer’s paragraph IV certification, then the FDA may finally approve the generic manufacturer’s ANDA upon satisfying itself as to the

bioequivalency of the generic to the brand-name drug. If, however, the patent owner initiates an infringement action against the ANDA filer within 45 days, then the FDA may not finally approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). Accordingly, a prompt disposition of such an action, as through a motion for summary judgment, may mean more rapid approval for a generic manufacturer subject to such a stay.

44. In turn, the Act encourages the challenge to branded drug patents and/or to design around them, by granting the first paragraph IV certified ANDA filer a 180-day period to exclusively market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. Under the regulations in place at the time Ranbaxy filed its ANDA for generic atorvastatin calcium, this "180-day exclusivity period" does not begin to run until either the first ANDA applicant enters the market with its generic equivalent, or a court enters a final judgment that the patent(s) subject to paragraph IV certification are invalid and not infringed. 21 U.S.C. § 355(j)(B)(iv).

45. Typically, AB-rated generic versions of brand name drugs are priced significantly below the brand name counterparts. Because of the price differentials, and other institutional features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their brand name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease significantly because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generics is dramatic.

46. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (i.e., the Hatch-Waxman Act) and most state legislatures (i.e., Drug Product Selection, or “DPS laws”), pharmacists may (and, in most states, must) substitute an AB-rated generic version of a drug for the brand name drug without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated “Dispense as Written,” or “DAW”). Indeed, both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously (a) engaging in the type of heavy promotion or “detailing” typically done by brand name manufacturers, and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

47. Generic competition enables direct purchasers to (a) purchase generic versions of brand name drugs at substantially lower prices, and/or (b) purchase the brand name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand name sales. Consequently, brand name drug manufacturers have a strong incentive to use various tactics, including the tactics alleged herein, to delay the introduction of AB-rated generic competition into the market.

VI. FACTUAL ALLEGATIONS

A. The Patents Related to Lipitor

48. Pfizer listed a total of six (6) patents covering Lipitor in the Orange Book: the ‘893 patent, the ‘995 patent, the ‘971 patent, the ‘104 patent, the ‘156 patent, and the ‘667 patent.

49. The '893 patent, which covered the active ingredient in Lipitor, expired on March 24, 2010.

50. The '995 patent (reissued as the '667 patent), which covered the particular form of the Lipitor molecule, expired on June 28, 2011.

51. Pfizer also owns the Process Patents (the '511 and '740 patents), which claim a process for making amorphous atorvastatin calcium that is limited to crystalline Form I atorvastatin calcium. The two Process Patents will expire in July 2016.

52. The first generic drug company to seek FDA approval to market a generic version of Lipitor was Ranbaxy, which filed ANDA No. 76-477 in August 2002. Ranbaxy was also first to make paragraph IV certifications as to all five patents listed at that time – the '893, '995, '104, '156, and '971 patents. In response, in 2003, Pfizer sued Ranbaxy for infringement of only the '893, and the '995 patents. *See Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 03-cv-209 (D.Del. 2003) (the "Lipitor Case").

53. Because it was the first to file an ANDA with paragraph IV certification for each listed patent, the Hatch-Waxman Act afforded Ranbaxy a 180-day exclusivity period to sell a generic version of Lipitor beginning on the earlier of (1) the date that of first commercial marketing of the drug, or (2) for each listed patent, on the date of a final court judgment declaring that patent invalid, unenforceable, or not infringed. During this 180-day exclusivity period, no other drug manufacturer can market a generic Lipitor product, with the exception of an authorized generic.

54. Because Pfizer listed the '104 and '971 patents in the Orange Book but did not file patent infringement suits against any generic ANDA filers who submitted paragraph IV certifications to those patents, Pfizer was able to ensure that (1) Ranbaxy's first-to-file

exclusivity would not be triggered by a court decision, and (2) Pfizer could prevent the launch of all other generics for an indefinite period by entering into an anticompetitive agreement with Ranbaxy whereby Ranbaxy agrees to delay the launch of its generic product.

55. Ranbaxy's first-to-file exclusivity has never been triggered because (1) Ranbaxy has not yet begun to market its product, and (2) no court decision of non-infringement or invalidity has been issued with respect to the '104, '156, and '971 patents.

56. Because Pfizer did not list the Process Patents in the Orange Book, they were never included in any generic manufacturers' paragraph IV certification and Pfizer could not obtain the Hatch-Waxman 30-month stay by bringing an infringement claim on these patents.

57. Ranbaxy and one other generic manufacturer, Mylan Pharmaceuticals Inc., were the only companies that Pfizer ever brought infringement actions against for the Process Patents. The lawsuit against Mylan was settled before the Court could make any substantive ruling on either process patent, and the terms of the settlement have not been publicly disclosed.

B. Pfizer's Lawsuits Against Ranbaxy

58. During the Lipitor Case, Pfizer moved for leave to amend its pleadings to add claims, under 35 USC §271(g), that Ranbaxy had also intended to infringe the Process Patents. Pfizer requested a declaratory judgment of infringement under 28 USC § 2201. *See Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 03-cv-209 (D.I. 41) (D.Del. 2003). Ranbaxy opposed Pfizer's motion to add the Process Patent claims, arguing that Pfizer had not made a sufficient allegation of immediacy and reality to establish the existence of an actual controversy (D.I. 44).

59. In an opinion issued in April 2004, the Court agreed with Ranbaxy, stating that, "because of the uncertainty surrounding Ranbaxy ANDA efforts, Pfizer's attempt to join claims under its '511 and '740 patents by invoking the Declaratory Judgment Act, 28 U.S.C. §2201, are

premature.” The Court further found that “waiting for any claims involving Ranbaxy’s manufacturing process to mature so that such claims comport with the immediacy and reality standard will not prejudice Pfizer in any way” (D.I. 139).

60. In 2005, after a bench trial, the district court found that Ranbaxy’s proposed generic would infringe both the ‘893 and ‘995 patents.

61. In August 2006, the Federal Circuit affirmed the district court’s finding that Ranbaxy’s proposed generic would infringe Pfizer’s ‘893 ingredient patent, but reversed the Court’s findings with respect to the ‘995 form patent, and invalidated claim 6 of the ‘995 patent.

62. As a result of the Federal Circuit’s decision, Pfizer’s patent protection for Lipitor was shortened from June 28, 2011 (derived from the invalidation of claim 6 of the ‘995 patent) to March 24, 2010, the expiration date for the ‘893 patent.

63. Thereafter, in January 2007, Pfizer filed a reissue application with the Patent and Trademark Office (“PTO”), seeking to amend the ‘995 patent to correct the technical defects found by the Federal Circuit and, thus, extend patent protection for Lipitor until June 28, 2011.

64. In May 2007, Ranbaxy filed a protest with the PTO against Pfizer’s reissue application.

65. In August 2007, the PTO issued a First Office Action rejecting Pfizer’s reissue application on grounds set forth in Ranbaxy’s protest—that certain claims in the ‘995 patent were anticipated, obvious, or constituted double-patenting.

66. Pfizer then filed a response to the PTO’s initial Office Action, which was again rejected by the PTO in April 2008.

67. Consequently, Ranbaxy intended to enter, and could have entered, the market with its generic immediately after March 24, 2010.

68. On March 24, 2008, nearly five years after it first attempted to attach the process patents to the Lipitor Case, and knowing that a court had already ruled that it lacked standing under 28 U.S.C. §§2201 and 2208, Pfizer again sued Ranbaxy for declaratory judgment of infringement of the Process Patents on *the same grounds* as those on which it based its original motion to amend the Lipitor Case pleadings. *See Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 08-cv-164 (D.Del. 2008) (D.I. 1, ¶¶ 31, 41).

69. Ranbaxy moved to dismiss for lack of subject matter jurisdiction arguing that the final judgment in the Lipitor Case, which permanently enjoined Ranbaxy from engaging in the manufacture, use, offer to sell or sale of its generic version of Lipitor until the expiration of the ‘893 patent, made “any harm to Pfizer from alleged infringement of the ‘511 and ‘740 patents *much less* imminent now than in the Lipitor case when the Court found no imminent threat of harm or injury.” (D.I. 10 at 9).

70. The Court never had an opportunity to make a substantive ruling on Ranbaxy’s Motion to Dismiss because on June 18, 2008, the parties filed a consent order resolving the lawsuit. (D.I. 19). The consent order referred to an agreement between Pfizer and Ranbaxy, dated June 17, 2008, “pursuant to which the parties have resolved this action and Pfizer has granted Ranbaxy certain rights to its portfolio of patents relating to atorvastatin.” (the “Agreement”) *Id.*

C. The Agreement

71. On or about June 18, 2008, Pfizer announced that it had entered into the Agreement with Ranbaxy to settle the Lipitor Case.

72. As of the date of the Agreement, Ranbaxy’s 180-day exclusivity period with respect to the ‘995 patent had been triggered and had expired, and its 180-day exclusivity period

with respect to the '893 patent was set to automatically terminate on the expiration of that patent on March 24, 2010.

73. As of the date of the Agreement, there was no Hatch-Waxman impediment that would have prevented a generic Lipitor launch by Ranbaxy, whether independently or in association with another manufacturer, on or after March 24, 2010.

74. And as of the date of the Agreement, the only means by which Pfizer could have prevented a launch by Ranbaxy on or after March 24, 2010 was by seeking an injunction. As far as Pfizer knew in 2008, obtaining such an injunction would have required a showing that Pfizer was likely to succeed on the merits of patent infringement claims that it had never previously asserted against Ranbaxy.

75. Under the terms of the Agreement, Ranbaxy was given a license to sell generic versions of Lipitor in the United States, effective November 30, 2011 — twenty months after the then-sole-principal and valid patent on Lipitor (the '893 patent) would have expired and Ranbaxy would have otherwise been able to sell its generic.

76. Additionally, Ranbaxy was given a license to sell generic versions of Lipitor on varying dates in several additional countries.

77. As additional consideration to enter into the Agreement, Pfizer forgave debts owed by Ranbaxy flowing from a court judgment or judgments Pfizer won against Ranbaxy on infringement claims unrelated to the Lipitor patents.

78. The Agreement further provided that Ranbaxy would refrain from any further challenges to the validity of patents related to Lipitor, including the reissue application for the '995 patent then pending before the PTO.

79. In January 2009, the PTO, without any objection by Ranbaxy, issued a Notice of Allowance accepting Pfizer's application for the '995 patent and reissuing the same as the '667 patent. This Notice of Allowance extended Pfizer's patent protection for Lipitor until June 28, 2011.

80. By delaying Ranbaxy's generic version of Lipitor in the United States — which, in the absence of the Agreement, would have been sold lawfully as early as March 24, 2010, but in no event later June 28, 2011 — Pfizer was able to sell Lipitor exclusively for up to 20 additional months, resulting in extra sales of Lipitor worth approximately \$10 billion dollars. In return, Pfizer granted Ranbaxy the right to distribute a generic substitute for Lipitor in foreign markets earlier than it would have been able to do so otherwise.

81. The Agreement denies purchasers, including Plaintiff and the Class, access to a generic substitute for Lipitor in the United States for up to 20 months following the expiration of the '893 patent. Lipitor's current price exceeds \$4 per day, while a generic version will sell for between \$0.25-\$0.35 and even as low as \$0.10. Consequently, Lipitor purchasers in the United States are paying, and will continue to pay, inflated prices for Lipitor through at least May of 2012.

82. By reason of these unlawful agreements, there is presently no generic competitor to Lipitor in the United States market. Prices for Lipitor are substantially higher since March 2010 than they would have been but for the Agreement.

83. Ranbaxy intends to launch its generic version of Lipitor in the American market in November 2011 risk-free and with market exclusivity for 180 days.

84. The Agreement between Defendants, which artificially extended Pfizer's exclusivity in the domestic atorvastatin calcium market, allocated markets between the

Defendants, artificially postponed price reductions, and restrained trade in the provision of Lipitor and its generic alternatives, is a violation of the Sherman Act.

85. The Agreement between Pfizer and Ranbaxy is an agreement to divide markets in that Ranbaxy agreed that it would not sell its generic in the United States until November 2011 in exchange for being able to sell in other countries.

86. The Agreement between Pfizer and Ranbaxy is an agreement to fix prices in that Pfizer would be able to charge many times more for Lipitor than it would otherwise have been able to charge in the absence of the unlawful agreement.

87. The Agreement between Pfizer and Ranbaxy is a combination to monopolize, an attempt to monopolize, and monopolization in that the Agreement unlawfully extends Pfizer's exclusivity in the domestic atorvastatin calcium market, excludes competition by other generics, and fixes the price of both the generic and branded versions of Lipitor.

88. The Agreement between Pfizer and Ranbaxy is alleged to restrain trade in that Pfizer allows Ranbaxy to sell generic Lipitor in countries other than the United States so long as it does not sell generic Lipitor in the United States, and forgives judgment debts that Ranbaxy owes to Pfizer as a result of unrelated patent disputes between the Defendants.

89. The Agreement between Pfizer and Ranbaxy is an abuse of the Hatch-Waxman Act in that it unlawfully delays the start of Ranbaxy's period of exclusivity and Ranbaxy agreed to misuse its exclusivity to delay other generic competitors from entering the market with their generic Lipitor products.

90. The Process Patent litigation was a sham designed to create the false impression to outsiders that Ranbaxy had incentive to enter into the Agreement with Pfizer in order to avoid

potential damages resulting from losing that litigation when, in fact, there was no real case or controversy and, consequently, Ranbaxy faced no real risk.

91. The Agreement meant that purchasers would continue to pay branded pharmaceutical prices for Lipitor longer than necessary.

92. The Agreement between Defendants extending the length of the Lipitor patents constitutes fraudulent procurement and enforcement of a patent in violation of the Sherman Act.

93. The Agreement between Defendants constitutes a market allocation agreement between competing providers of Lipitor and its generic equivalent to illegally restrain trade in violation of the Sherman Act.

VII. EFFECT ON INTERSTATE COMMERCE

94. At all material times, Lipitor, manufactured and sold by Pfizer, was shipped across state lines and sold to customers located outside its state of manufacture.

95. During the relevant time period, in connection with the purchase and sale of Lipitor, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

96. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint were within the flow of, and have substantially affected, interstate commerce.

VIII. RELEVANT MARKET

97. Direct proof exists that Pfizer had monopoly power over the price of atorvastatin calcium. Such direct evidence will include, inter alia, (a) manufacturers' and/or market-wide transactional data that will show a significant, non-transitory decline in atorvastatin calcium prices upon entry of generic atorvastatin calcium that had not occurred until generic entry, and (b) abnormally high price-cost margins enjoyed by Pfizer prior to the entry of generic competition. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether Pfizer had monopoly power.

98. Assuming, *arguendo*, that a relevant market needs to be defined, the relevant product market is all atorvastatin calcium products – i.e., Lipitor (in all its forms and dosage strengths), and bioequivalent atorvastatin calcium products. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Pfizer's ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which atorvastatin calcium is prescribed.

99. Through the anticompetitive conduct alleged herein, Defendant was able to profitably charge supra-competitive prices for atorvastatin calcium without losing substantial sales, and thus, by definition, maintained monopoly power with respect to atorvastatin calcium sold in the United States.

100. Pfizer's market share in the relevant market is 100%.

**IX. FIRST CAUSE OF ACTION
VIOLATION OF SECTIONS 2 OF THE SHERMAN ACT AGAINST ALL
DEFENDANTS
(15 U.S.C. § 2)**

101. Plaintiff incorporates and realleges all paragraphs in this Complaint, as though fully set forth below.

102. Defendants combined, conspired and contracted between and among themselves to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and Pfizer did in fact monopolize trade in the United States in the market for atorvastatin calcium, and to eliminate competition in the sale of Lipitor and its generic equivalents in the United States.

103. Defendants, their agents and affiliates and co-conspirators, both known and unknown, entered into and engaged in a continuing unlawful trust in restraint of trade and commerce in Lipitor and its generic equivalents, in violation of the Sherman Act by entering into agreements to extend patent monopolies and to divide markets and allocate customers.

104. The purpose and effect of such agreements was to fix, raise, stabilize and maintain the prices for Lipitor and its generic equivalents at supra-competitive levels, which increased prices paid by Plaintiff and the Class.

105. During the period covered by this Complaint and thereafter, Plaintiff and the Class purchased Lipitor and will continue to purchase Lipitor, and by reason of the alleged violation of the antitrust laws, Plaintiff paid more and will pay more for these drugs than they would have paid in the absence of the illegal trust, combination and agreement. As a proximate result cause thereof, Plaintiff has been injured and will continue to be injured in its business and property and have suffered damages in an amount according to proof at trial.

**X. SECOND CAUSE OF ACTION
VIOLATION OF SECTIONS 2 OF THE SHERMAN ACT AGAINST PFIZER
(15 U.S.C. § 2)**

106. Plaintiff incorporates and realleges Paragraph's 1-97 in this Complaint, as though fully set forth below.

107. Defendant Pfizer used various, willful and exclusionary means as part of a scheme described herein to improperly maintain and extend its monopoly power in the atorvastatin calcium market, as detailed above.

108. The goal, purpose and/or effect of Pfizer's scheme was to prevent, delay and/or minimize the success of the entry of generic atorvastatin calcium competitors which would have sold generic atorvastatin calcium in the United States at prices significantly below Pfizer's prices for Lipitor, which would have effectively caused the average market price of atorvastatin calcium to decline dramatically.

109. The goal, purpose and/or effect of Pfizer's scheme was also to maintain and extend Lipitor's monopoly power with respect to atorvastatin calcium. Pfizer's illegal scheme to prevent, delay and/or minimize the success of the introduction into the United States marketplace of any generic version of Lipitor enabled Pfizer to continue charging supra-competitive prices for atorvastatin calcium without a substantial loss of sales.

110. As a result of Pfizer's illegal conduct, Plaintiff and the Class paid more than they would have paid for atorvastatin calcium, absent Pfizer's illegal conduct. But for Pfizer's illegal conduct, competitors would have begun marketing versions of atorvastatin calcium well before they actually did, and/or would have been able to market such versions more successfully.

111. If manufacturers of generic atorvastatin calcium entered the market and competed with Lipitor in a full and timely fashion, Plaintiff and other Class members would have

substituted lower-priced generic atorvastatin calcium for the higher-priced brand name Lipitor for some or all of their atorvastatin calcium requirements, and/or would have received lower prices on some or all of their remaining Lipitor purchases.

112. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Lipitor directly from Pfizer. As a result of Pfizer's illegal conduct alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their atorvastatin calcium requirements. Plaintiff and all of the other Class members paid prices for atorvastatin calcium that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower priced generic atorvastatin calcium instead of expensive brand name Lipitor; (2) Class members were forced to pay artificially inflated prices for generic atorvastatin calcium; and/or (3) the price of branded Lipitor was artificially inflated by Defendants' illegal conduct.

113. Lipitor's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for atorvastatin calcium in the United states, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2

XI. THIRD CAUSE OF ACTION VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. §1)

114. Plaintiff incorporates and realleges Paragraph's 1-97 in this Complaint, as though fully set forth below.

115. Beginning in or about March of 2008, Pfizer and Ranbaxy engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of atorvastatin calcium in the United states to Pfizer;

(b) prevent the sale of a generic version of atorvastatin calcium in the United States until at least November 30, 2011, thereby protecting Lipitor from any generic competition for up to 20 months; and (c) fix the price at which Plaintiff and the other members of the Class would pay for Lipitor at the higher, branded price.

116. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' agreements are horizontal market allocation and price fixing agreements between actual or potential competitors and thus are *per se* violations of Section 1. In the alternative, Defendants' agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.

117. Plaintiff and all members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiff and the Class members have paid more on their purchases of Lipitor than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lipitor.

118. As a result of Defendants' illegal conduct, Plaintiff and the Class paid more than they would have paid for atorvastatin calcium, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of atorvastatin calcium well before November 30, 2011, and/or would have been able to market such versions more successfully.

119. If manufacturers of generic atorvastatin calcium entered the market and competed with Lipitor in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic atorvastatin calcium for the higher-priced brand name Lipitor

for some or all of their atorvastatin calcium requirements, and/or would have paid lower prices on some or all of their remaining Lipitor purchases.

120. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Lipitor directly from Pfizer. As a result of Pfizer's illegal conduct, alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their atorvastatin calcium requirements. Plaintiff and the other Class members paid prices for atorvastatin calcium that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic atorvastatin calcium instead of expensive brand name Lipitor; (2) Class members were forced to pay artificially inflated prices for generic atorvastatin calcium; and/or (3) the price of brand name Lipitor was artificially inflated by Defendants' illegal conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, prays for judgment against all Defendants, jointly and severally, as follows:

1. That the Court adjudge and decree that the Defendants and each of them have violated Sections 1 and 2 of the Sherman Antitrust Act;
2. That the Plaintiff and all others similarly situated be awarded damages suffered by reason of these violations and that those damages be trebled in accordance with the law;
3. That the Plaintiff be awarded reasonable attorneys' fees and costs;
4. That any and all patents held by Defendants Pfizer or Warner Lambert with regard to Lipitor be declared null and void and have no further effect;

5. That any and all rights that Ranbaxy may have under the Hatch-Waxman Act be declared null and void and of no further effect; and

6. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims and complaints in this Complaint so triable.

DATED: November 17, 2011

Respectfully Submitted,

s/ Peter S. Pearlman
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